Patent
Attorney's Docket No. 003300-794

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	
Johan WANSELIN et al.	Group Art Unit: 1744
Application No.: 09/879,117	Examiner: M. R. Chorbaji
Filed: June 13, 2001	Confirmation No.: 3882
For: DEVICE FOR AN AUTOCLAVE	

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Johan Wanselin, declare:

(1) That I am a Swedish citizen residing at Toftenäs 1, SE 471 31 Skärhamn, Sweden.

(2) That I have a 25 years documented experience in technical development and construction in general and a five years specific experience in construction of sterilization devices.

(3) That I am currently employed by Getinge Skärhamn AB as Development Manager.

(4) That I have read and am familiar with the above-identified United States patent application filed on June 13, 2001, entitled Device For An Autoclave. I have also read and am familiar with U.S. Patent No. 4,919,888 (*Spence*) which was cited in the present application by Examiner Chorbaji of the U.S. Patent and Trademark Office.

(5) I understand that the Examiner has relied on *Spence* for disclosing a sterilization container for use as a sterilization chamber. I understand that the container of Spence uses a microorganism proof seal (a gasket) between the lid and the base and a belt of shrinkable material (abstract line 1-6). In col. 5 lines 20-22 in *Spence*, such belts of PVC would be three and one-half mills thick. Further, the belt for the microorganism proof seal is shrunk sealed in about 10 seconds (col. 6 line 39) or alternatively sealed before inserted into a sterilizing device (col. 6 lines 49-52). I understand that filter means (col. 3 lines 41-45) additionally has to be used in the container by *Spence* in order to perform a sterilization, wherein such filter means permits entry and exit of sterilant but which do not permit entry of microorganisms (col. 3 lines 36-41). Also, the container by *Spence* is opened by cutting the belt of seals by using a knife along the seam (col. 6 line 53-56).

(6) A sterilization device, e.g. a device using steam as a sterilant during a pressurization phase, must comprise a sterilization pressure chamber (in which objects like containers or the like can be sterilized). Sterilization pressure chambers are pressure vessels, and as such, they must fulfill national safety requirements and be certified and evaluated under a so-called ASME evaluation with a Finite-Element-Analysis. The attached ASME Section VIII Certificate (Appendix 1) and Finite-Element-Analysis (Appendix 2) discloses the evaluation of a pressure chamber made of metal (stainless steel) which is the material normally used for a sterilization pressure chamber. According to the enclosed evaluation of ASME Section VIII, the pressure chamber made of solid stainless steel with a chamber thickness of 5 mm, is approved for 50,000 pressure cycles from –1.0 to 2.2 bar.

(7) In my expert opinion, one of ordinary skill in the art would reasonably conclude, based on the disclosure of *Spence* and the ASME Section VIII evaluation discussed above, that *Spence* does not disclose a sterilization chamber, as that term is understood in the art.

(8) The time for a sterilization process is normally about 15 minutes and must comprise several cycles of a pressurization phase and a vacuum phase (normally 5 cycles). Thus, the above mentioned 10 seconds for sealing the container by *Spence* is not considered sufficient to perform a sterilization process. Accordingly, the container in *Spence* must also comprise the above-discussed filter means which permits entry and exit of sterilant. As such, the container disclosed in *Spence* is not considered structurally to be a sterilization pressure chamber, as that term is understood by one of ordinary skill in the art.

(9) The structure defining the container in *Spence* has to be placed in a sterilization pressure chamber of a sterilization device in which the pressure chamber is pressurized during a sterilization process, and the filter means equalizes the pressure inside and outside the container. As the container disclosed in *Spence* has to be placed in a sterilization pressure chamber of a sterilization device, the interior of the container can neither be subjected to, nor is suitable to be subjected to, a higher pressure (the interior pressurized) than the surrounding pressure of the container. Thus, it is evident that the container in *Spence* is not suitable for connection to a sterilant source for achieving an interior pressurization, but can merely be subjected to an ambient pressure in a sterilization chamber.

(10) In my opinion as one skilled in the art, if the interior of the container disclosed in *Spence* were to be pressurized, the filter means would not (and should not)

withstand the interior pressure. Additionally the gasket between the lid and the base is only a microorganism seal (not adapted for an interior pressure, especially not for pressurization cycles described above). Comparing the structure of the above-mentioned seal belts of PVC (three and one-half mills thick) and the above-discussed ASME Evaluation of a sterilization pressure chamber (5 mm thick solid stainless steel), the belts of the container in *Spence* is considered neither able to nor suitable to withstand such interior pressure, especially not for a multiple pressure cycles.

(11) I also note that the container by *Spence* is opened by cutting the seal with a knife each time when used. As the *Spence* container comprises filter means and the microorganism proof seal (the gasket) between the lid and the base, there is no need for the container to withstand the same interior pressure as which a sterilization pressure chamber is submitted to. In fact, *Spence* does not mention that the container itself nor that the walls defining the container is constructed to withstand an internal pressure as a pressure chamber (pressure vessel), especially not the pressure cycles according to the ASME Evaluation above. Thus, the *Spence* container is not considered structurally to be a sterilization pressure chamber by one of ordinary skill in the art. Accordingly, the *Spence* container does not define a sealed pressure chamber which interior is pressurized and which sterilization chamber is releasably fastened within the sterilization device, as in the presently claimed invention.

(12) I further declare that all statements made herein of my own knowledge are true and that all statements on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 30-03-2005

Johan Wanselin

TÜV TÜV Rheinland Group

Design Examination Statement

Application of ASME VIII Division I and II Edition 2001

Statement Number 973 / 031762 K7

Name and Address of the Manufacturer	**GETINGE Skärhamn AB** **Industriv. 5** **SE 471 21 Skärhamn** **SWEDEN**

Herewith is stated that the design of the below described pressure vessel complies with the relevant parts of ASME Section VIII, Divisions I and II, Edition 2001

Description of the Pressure Vessel:	**Pressure Vessel K7 of rectangular cross section**
Examination Report:	**973-031762**
Drawing No.:	**48320109, 4839833, 4839834, 4839913, 48320013**
Applications:	**Design Pressure: -1 / 2.4 bar**
	Design Temperature: 140°C
	50,000 Variations of Pressure from –1.0 to 2.2 bar
	Test Pressure: 3.8 bar
	Medium: Steam

Cologne, 15th December 2003

Business Field Strength, Design Examination and FE-Calculation

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